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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/809,869

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Osama Kandil

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EXAMINER

JEAN-LOUIS, SAMIRA JM

ART UNIT

PAPER NUMBER

1617

NOTIFICATION DATE

DELIVERY MODE

08/06/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chalin@smithpatent.com

Office Action Summary	Application No. 10/809,869	Applicant(s) KANDIL, OSAMA	
	Examiner SAMIRA JEAN-LOUIS	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-11, 18-21, 26, 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-11, 18-21, 26, and 28-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continuation Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 03/09/09 and 05/14/09 have been entered.

Response to Arguments

This Office Action is in response to the amendment submitted on 03/09/09 and the Remarks submitted on 05/14/09. Claims 9-11, 18-21, 26, and 28-29 are currently pending in the application, with claims 1-8, 12-17, 22-25, and 27 having being cancelled. Accordingly, claims 9-11, 18-21, 26, and 28-29 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

Terminal Disclaimer

The terminal disclaimer (TD) filed on 03/09/09 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of

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U.S. patent application 12/043052 has been reviewed and is accepted. The terminal disclaimer has been recorded. As a result of the approval of the TD, the Obviousness Double Patenting (ODP) is hereby withdrawn.

1. Applicant's argument with respect to Ahmad who does not suggest to one of ordinary skill in the art the use of *Nigella sativa* extracts for the treatment of skin diseases has been fully considered but is not found persuasive. Ahmad teaches that members of *Ranunculaceae* family are known to be used for a variety of conditions *inter alia* skin diseases (see Ahmad pg. 3, paragraph 0019). *Nigella sativa* is a member of the *Ranunculaceae* family and its extract is taught by Ahmad as a composition. Consequently, the Examiner maintains that one of ordinary skill in the art would have found it obvious to try extracts of *Nigella sativa* for the treatment of skin diseases since Ahmad teaches that members of this family are effective in treating skin diseases. Moreover, one of ordinary skill in the art would have expected a reasonable expectation of success since Ahmad discloses the effective use of members of the *Ranunculaceae* family in skin treatments. In fact, Goreja teaches that the "Black Seed" (i.e. another name for *Nigella sativa*) is useful for a variety of conditions among which are skin ailments wherein the "Black Seed" is efficacious in allergic skin reactions helpful in reducing itching and inflammation, preventing infection and in healing the skin in various skin conditions including eczema, psoriasis, skin fungi, and infections (see pgs. 33 and 37). Goreja reflects the state of the art at the time of the invention and reflects what was known to one of ordinary skill in the art at the time of the invention. As a result, the

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Examiner maintains that one of ordinary skill in the art would have indeed found it obvious to try *Nigella sativa* extracts to treat skin conditions/diseases in light of the disclosures of Ahmad and Goreja.

As for applicant's arguments that Ahmad does not teach a polyunsaturated fatty acid fraction extracted from *Nigella sativa*, the Examiner maintains that Ahmad teaches the use of *Nigella Sativa* extracts in his compositions that is initially treated to obtain the extract (see Ahmad pg. 15, paragraph 0129). Thus, the Examiner maintains that such extraction necessarily contains the polyunsaturated fatty acid fraction as Ahmad does not teach separation of the solid fraction from the liquid fraction.

2. Applicant's arguments that the genus does not fairly suggest the claimed species have been fully considered but are not found persuasive. While the teachings of Ahmad do not discuss the role of *Nigella sativa* in skin diseases, Ahmad nonetheless teaches that members of the *Ranunculaceae* family can be used for skin treatments and Ahmad further cites *Nigella sativa* as a member of this family. As a result, the Examiner contends that such disclosure would have indeed motivated one of ordinary skill in the art to try *Nigella sativa* in treating skin diseases and further expect such treatment to be successful since Ahmad teaches that it is well known that members of this family can be used for skin diseases. Thus, regardless if an explicit statement was not made by Ahmad regarding *Nigella sativa* (hence the reason for an obviousness rejection as opposed to an anticipatory rejection), the disclosure of Ahmad would have prompted one of ordinary skill in the art to try *Nigella sativa* for the treatment of skin diseases.

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As for applicant's arguments that Ahmad does not teach a specific extract, the Examiner again reiterates the aforementioned response which is that Ahmad teaches treatment and extraction of *Nigella sativa* and Ahmad does not disclose separation of the solid fraction from the liquid fraction. As a result, the polyunsaturated fatty acid fraction claimed by applicant will necessarily be present in the extract of Ahmad. Thus, for these reasons, the Examiner asserts that Ahmad does indeed render obvious applicant's invention.

3. Applicant arguments that there is no reasonable expectation of success and that Ahmad does not suggest a topical semi-solid formulation have been fully considered but are not found persuasive. In his disclosure, Ahmad clearly teaches the use of a solution of plant extract (which includes *Nigella sativa*) for topical delivery in the form of a hydrogel lotion or cream (see Ahmad, pg. 11, paragraph 0092; pg. 4, paragraph 0029; pg. 3; paragraph 0019; and pg. 1, paragraph 001). Because a hydrogel is a semisolid formulation, such recitation does indeed read on applicant's claims. Additionally, Ahmad explicitly teaches that compositions which can contain *Nigella sativa* can be formulated as semi-solid compositions (pg. 10, paragraphs 0082 and 0087). Moreover, given that Ahmad teaches that members of the Ranunculaceae family which includes *Nigella sativa* can be used for a variety of conditions including skin diseases, one of ordinary skill in the art would have indeed be motivated to try *Nigella sativa* for the treatment of skin diseases and expect that such member would work in treating such

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types of diseases since other members have been efficacious in treating the same disease types.

As for applicant's arguments that Ahmad does not disclose a purified polyunsaturated fatty acid fraction, such arguments are again not found persuasive since Ahmad does teach treatment of *Nigella sativa* plant material followed by extraction and concentration (see Ahmad pg. 15, paragraph 0129). Given that the claims as previously presented recited that the composition comprised a purified polyunsaturated fatty acid fraction, the Examiner maintains that the extract of Ahmad necessarily comprised a purified polyunsaturated fatty acid fraction. As for applicant's claims that such fraction should be devoid of contaminants, the Examiner respectfully points out that Ahmad does teach that vegetative material was discarded and thus contaminants were therefore excluded. If applicant however is referring to a purified polyunsaturated fatty acid fraction devoid of saturated fatty acids, sterols, volatile oils and glyceryl, such arguments are moot as applicant is referring to the newly amended claims. It is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Consequently, the Examiner maintains that the rejection was indeed proper.

For the foregoing reasons, the ODP rejection is hereby withdrawn. The 103 (a) rejections were indeed proper. However, in view of applicant's amendment, the following modified 103 (a) Non-Final rejections are being made.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

As for the term “consisting essentially of” limitation in claim 9 and 28, for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.” See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d. If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of “consisting essentially of,” applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

Claims 9-11, 18-21 and 26 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Ahmad et al. (U.S. 2005/0058735 A1, previously submitted) in view of Goreja (Black Seed: Nature's Miracle Remedy, 2003, pgs. 33-42) and in further view of Berg (Advances in Dermatology, 1988, pg. 75-98, previously submitted) and Schlenk et al. (J. of Amer. Chem. Soc. 1950, Vol. 72, pg. 5001-5004, previously submitted).

Ahmad et al. teach that many members of the family Ranunculaceae can be used for treatment of a variety of conditions including skin diseases (see pg. 3, paragraph 0019). Ahmad et al. also teach novel compositions of botanicals that are members of the Ranunculaceae and extracts derived from these plants and that exhibit immunomodulatory activities (see pg. 3, paragraphs 0019). The compositions comprise botanicals from members of the Ranunculaceae which include *Nigella sativa* or extracts thereof along with a pharmaceutically acceptable carrier (see pg. 3, paragraph 0019-0020). The compositions of Ahmad et al. can be administered topically (see pg. 1, paragraphs 001, 0019 and 0029), formulated as a semi-solid composition (see pg. 10, paragraph 0082; formulated as a hydrogel which is a semi-solid composition; (paragraphs 0087 and 0092) and can contain emulsifying agents (instant claim 21, paragraph 0068), surfactants (i.e. stabilizing agents; instant claim 21, paragraph 0085), and preservatives (instant claim 21; see pg. 8, paragraph 0065). Ahmad et al. exemplified the composition containing *Nigella sativa* L. where *Nigella* seeds, leaves, flowers and stems are treated, extracted and the liquid extract is concentrated and the vegetative materials are discarded. Consequently, this crude extraction necessarily contains the polyunsaturated fatty acid fraction (instant claim 9; see pg. 14-15, paragraph 00127-00129). Importantly, the botanical ingredients of *Nigella sativa* extracts are in a concentration of not less than 20% weight by volume and this necessarily suggests that the polyunsaturated fatty acid fraction is in an amount of no less than 20% and this necessarily meets the limitation of claims 18-20 and 26 (instant

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claims 18-20 and 26; see abstract and paragraph 0024 and 00129).

Ahmad et al. do not specifically teach that *Nigella sativa* extract can be used for skin conditions or a method of treating a particular skin condition such as diaper rash (the elected species) or skin conditions arising from bacterial infection, fungal infection, allergic reaction or inflammation. Additionally, Ahmad et al. do not teach a purified polyunsaturated fatty acid fraction of *Nigella L. sativa* seeds free of saturated fatty acids, sterols, volatile oils and glyceryl esters.

Goreja teaches that the "Black Seed" (i.e. another name for *Nigella sativa*) is useful for a variety of conditions among which are skin ailments wherein the "Black Seed" is efficacious in allergic skin reactions, helpful in reducing itching and inflammation, preventing infection and in healing the skin in various skin conditions including eczema, psoriasis, skin fungi, and infections (see pgs. 33 and 37). Goreja has been provided to demonstrate the state of the art of *Nigella Sativa* and its role in skin diseases at the time of applicant's invention.

Berg, on the other hand, teaches that common diaper dermatitis (i.e. diaper rash) entails a group of inflammatory disorders (i.e. disorders as a result of the immune system) that affect the skin covered by diapers (i.e. diaper rash is a skin disorder; instant claim 11, see pg. 75, paragraph 01). Furthermore, Berg teaches that many dermatological conditions can occur in the diaper area including skin disorders such as

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seborrheic dermatitis (non-elected species of claim 11), atopic dermatitis (non-elected species of claim 11), impetigo (bacterial skin infection, i.e. skin infection arising from bacterial skin infection; instant claim 9) and microbial infections (which entails bacterial, fungal infections, etc...; instant claim 9) and this necessarily meets the limitation of claims 9 and 11 (see pg. 76, section of Dermatoses in the Diaper area).

Schlenk et al. teach a method of extracting polyunsaturated acid fraction from saturated fatty acids using a urea complex to yield a polyunsaturated fatty acid fraction devoid of saturated fatty acids and glyceryl esters and highly enriched (i.e. purified fraction; instant claim 9, see pg. 5001-5002). Schlenk et al. further teach that separation of the saturated from the polyunsaturated fatty acid fraction leads to enrichment of each type of fatty acid fraction from natural oils (see pg. 5003, paragraph 2).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize the method of Ahmad et al. utilizing *Nigella sativa* extract to treat diaper rash since Ahmad et al. teach the use of compositions of members of Ranunculaceae such as *Nigella sativa* or extracts thereof for treating skin diseases, and Goreja teaches the use of *Nigella sativa* for skin ailments, and Berg teaches that diaper rash is a skin disease characterized by inflammation. Moreover, one of ordinary skill would have found it obvious to utilize the method of Schlenk et al. for isolating the purified polyunsaturated fatty acid fraction since Schlenk et al. teach that urea complexes are capable of enriching the fatty acid fraction and thus isolating particular

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fractions. Thus, given the teachings of Ahmad, Goreja, Berg, and Schlenk, one of ordinary skill would have been motivated to utilize the *Nigella sativa* extract composition of Ahmad et al. for treating diaper rash given the disclosure of Ahmad, Goreja, and Berg and utilize the method of Schlenk et al. to isolate the polyunsaturated fraction with the reasonable expectation of providing a method that is not only efficient in treating diaper rash but also a method that is also useful in treating intertrigo, dermatitis, bacterial and fungal infections affecting the skin.

Regarding the skin moisturizing, revitalizing and analgesic effects as recited in claim 10, it is considered that one of ordinary skill in the art at the time of the invention was made would have found it obvious to conclude that the method of treating a skin condition using the extracted composition of Ahmad et al. would possess the same sensory and pharmacokinetic profiles as that disclosed by applicant since Ahmad et al. uses the same exact *Nigella sativa* L. seeds and such characteristics are properties of *Nigella sativa* L. seeds and a property is inseparable from the parent compound.

It is noted that In re Best, 195 USPQ 430, and In re Fitzgerald, 205 USPQ 594, discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmad et al. (U.S. 2005/0058735 A1, previously submitted) in view of Goreja (Black Seed: Nature's Miracle Remedy, 2003, pgs. 33-42) and in further view of Berg (Advances in Dermatology, 1988, pg. 75-98, previously submitted) and Schlenk et al. (J. of Amer. Chem. Soc. 1950, Vol. 72, pg. 5001-5004, previously submitted) as applied to claims 9-11, 18-21 and 26 above and in further view of Nickavar et al. (Z. Naturforsch. 2003, Vol. 58c, pg. 629-631, previously submitted).

The Ahmad, Goreja, Berg, and Schlenk references are as discussed above and incorporated by reference herein. However, Ahmad, Berg, and Schlenk do not teach the particular components contained in the polyunsaturated fatty acid fraction.

Nickavar et al. teach that the chemical composition of the fixed oil (i.e. saponified fraction-see table 1 of applicant) of *Nigella sativa* L. comprises 23.4% of oleic acid (i.e. octadecenoic acid) and 55.6% of linoleic acid (i.e. octadecadienoic acid)(instant claims 28-29). Nickavar has been provided to demonstrate that the polyunsaturated fatty acid fraction of *Nigella sativa* L extract utilized by Ahmad necessarily contains octadecenoic acid and octadecadienoic acid in the aforementioned ranges and this necessarily meets the limitation of claims 28-29.

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Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize the composition of Ahmad as evidenced by Nickavar et al. (given the specific ingredients contained in the polyunsaturated fatty acid fraction disclosed by Nickavar) to treat diaper rash in view of the knowledge of diaper rash as a skin disease and inflammatory disorder provided by Berg. Thus, given the teachings of Ahmad and Goreja who teach the use members of Ranunculaceae such as *Nigella sativa* to treat skin diseases and given that *Nigella sativa L.* is a member of the aforementioned family that contains 23.4% of octadecenoic acid and 55.6% of octadecadienoic acid of polyunsaturated fatty fraction (as taught by Nickavar et al.), and Berg discloses that diaper rash is a type of skin disease with an inflammatory component, one of ordinary skill would have been motivated to utilize the composition of Ahmad et al. given the disclosure of Ahmad, Goreja, and Nickavar to treat diaper rash given the disclosure of Berg with the reasonable expectation of providing a method that is not only efficient in treating various skin conditions including diaper rash but also a method that contains a highly enriched polyunsaturated fatty acid fraction.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

07/31/2009

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617